

## CLAIMS

What is claimed is:

1. A method for simulating and modeling a batch processing manufacturing facility, comprising the steps of:
  - 5 (1) selecting a sequence of unit operations, wherein each of said sequence of unit operations has an identifier code, wherein each unit operation includes one or more tasks required to execute a particular unit operation, wherein said tasks include a scheduling calculation for determining the duration of a particular task;
  - 10 (2) selecting a set of scheduling cycles for each of said sequence of unit operations;
  - (3) defining an offset for each of said scheduling cycles;
  - (4) referencing a master table using said identifier code to obtain operational parameters for each of said sequence of unit operations;
  - 15 (5) generating a block flow diagram using said sequence of unit operations and said operational parameters; and
  - (6) generating a process time line using said operational parameters, said block flow diagram, said set of scheduling cycles, said offsets and said tasks for each of said sequence of unit operations, wherein said tasks  
20 include a unit operation set up task, a unit operation execution task, and a unit operation clean up task, and wherein said process time line is primarily impacted by each said unit operation execution task relative to a respective offset, wherein said unit operation set up tasks and said unit operation clean up tasks impact said process time line secondarily in a  
25 back calculating and forward calculating manner with respect to corresponding unit operation execution tasks, respectively, whereby said process time line is used as a tool for batch processing, facility design and/or resource planning.

2. The method of Claim 1 wherein the batch process manufacturing facility is a biopharmaceutical batch processing facility.
3. The method of Claim 1 further comprising the step of defining a Current Critical  
5 Path Start time (CCPS), wherein said CCPS is the start time for a first unit operation execution task in a current unit operation being evaluated by a scheduling procedure.
4. The method of Claim 3 further comprising the steps of (1) defining a lot cycle as  
10 a set of two or more unit operations that cycle together as a subset of a process cycle, wherein said process cycle includes unit operations that generate crude product, (2) determining a lot cycle offset for scheduling unit operations and their respective tasks associated with a lot cycle, and (3) applying said lot cycle  
15 offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said lot cycle.
5. The method of Claim 4 further comprising the steps of (1) defining a batch cycle  
20 as a set of two or more unit operations that cycle together as a subset of a lot cycle, (2) determining a batch cycle offset for scheduling unit operations and their respective tasks associated with a batch cycle, and (3) applying said batch cycle offset to a CCPS associated with each said unit operation in order to  
25 schedule said tasks within said process time line if said unit operation is part of said batch cycle.
6. The method of Claim 5 further comprising the steps of (1) defining a cluster -  
main cycle as a set of two or more unit operations that cycle together within a batch cycle or lot cycle and process the entire quantity of batch material with  
30 each main cycle iteration, (2) determining a cluster- main cycle offset for scheduling two or more unit operations and their respective tasks associated

with a cluster - main cycle, and (3) applying said cluster – main cycle offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said cluster– main cycle.

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7. The method of Claim 6 further comprising the steps of (1) defining a cluster - sub cycle as a set of two or more unit operations that cycle together within a cluster - main cycle, batch cycle or lot cycle and process a proportionately smaller (partial) quantity of total input material to the unit operation with each sub cycle iteration, (2) determining a cluster – sub cycle offset for scheduling two or more unit operations and their respective tasks associated with a cluster - sub cycle, and (3) applying said cluster – sub cycle offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said cluster – sub cycle.

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8. The method of Claim 7 further comprising the steps of (1) nesting 2 or more cluster – main cycles with associated cluster – sub cycles within each other, (2) determining a cluster – main cycle offset for scheduling two or more unit operations and their respective tasks associated with a nested cluster – main cycle, (3) determining a cluster – sub cycle offset for scheduling two or more unit operations and their respective tasks associated with a cluster – sub cycle that is associated with a respective nested cluster – main cycle, and (4) applying said cluster – main cycle offsets and associated cluster – sub cycle offsets to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said nested cluster – main cycle and/or respective cluster – sub cycle.

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9. The method of Claim 8 further comprising the steps of (1) defining a unit operation– main cycle within a nested or non-nested cluster– main cycle and/or associated cluster– sub cycle, a batch cycle or a lot cycle, (2) determining a unit

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- operation offset for scheduling said one or more tasks associated with a unit operation— main cycle, and (3) applying said unit operation offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said unit operation— main cycle.
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10. The method of Claim 9 further comprising the steps of (1) defining a unit operation – sub cycle within a respective unit operation – main cycle, a nested or non-nested cluster – main cycle and/or associated cluster – sub cycle, a batch cycle or a lot cycle, as unit operation that cycles within a unit operation - main cycle and processes a proportionately smaller (partial) quantity of total input material to the unit operation with each sub cycle iteration, (2) determining a unit operation offset for scheduling said one or more tasks associated with a unit operation – sub cycle, and (3) applying said unit operation offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said unit operation— sub cycle.
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11. A system for simulating and modeling a batch processing manufacturing facility, comprising:
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- means for selecting a sequence of unit operations, wherein each of said sequence of unit operations has an identifier code, wherein each unit operation includes one or more tasks required to execute a particular unit operation, wherein said tasks include a scheduling calculation for determining the duration of a particular task;
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- means for selecting a set of scheduling cycles for each of said sequence of unit operations;
- means for defining an offset for each of said scheduling cycles;
- means for referencing a master table using said identifier code to obtain operational parameters for each of said sequence of unit operations;
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means for generating a block flow diagram using said sequence of unit operations and said operational parameters; and

5 means for generating a process time line using said operational parameters, said block flow diagram, said set of scheduling cycles, said offsets and said tasks for each of said sequence of unit operations, wherein said tasks include a unit operation set up task, a unit operation execution task, and a unit operation clean up task, and wherein said process time line is primarily impacted by each said unit operation execution task relative to a respective offset, wherein  
10 said unit operation set up tasks and said unit operation clean up tasks impact said process time line secondarily in a back calculating and forward calculating manner with respect to corresponding unit operation execution tasks, respectively, whereby said process time line is used as a tool for batch processing, facility design, and/or resource planning.

15 12. The system of Claim 11 further comprising means for defining a Current Critical Path Start time (CCPS), wherein said CCPS is the start time for a first unit operation execution task in a current unit operation being evaluated by a scheduling procedure.

20 13. The system of Claim 12 further comprising means for defining a lot cycle as a set of two or more unit operations that cycle together as a subset of a process cycle, wherein said process cycle includes unit operations that generate crude product, means for determining a lot cycle offset for scheduling unit operations and their respective tasks associated with a lot cycle, and means for applying  
25 said lot cycle offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said lot cycle.

14. The system of Claim 13 further comprising means for defining a batch cycle as a  
30 set of two or more unit operations that cycle together as a subset of a lot cycle,

wherein said process cycle includes unit operations that generate crude product, means for determining a batch cycle offset for scheduling unit operations and their respective tasks associated with a batch cycle, and means for applying said batch cycle of met to a CCPS associated with each said unit operation in order to  
5 schedule said tasks within said process time line if said unit operation is part of said batch cycle.

15. The system of Claim 14 further comprising means for defining a cluster– main cycle as a set of two or more unit operations that cycle together within a batch  
10 cycle and process the entire quantity of batch material with each main cycle iteration, means for determining a cluster cycle offset for scheduling two or more unit operations and their respective tasks associated with a cluster– main cycle, and means for applying said cluster cycle offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process  
15 time line if said unit operation is part of said cluster– main cycle.

16. The system of Claim 15 further comprising means for defining a cluster - sub cycle as a set of two or more unit operations that cycle together within a cluster -  
main cycle, batch cycle or lot cycle and process a proportionately smaller  
20 (partial) quantity of batch material with each sub cycle iteration, means for determining a cluster – sub cycle offset for scheduling two or more unit operations and their respective tasks associated with a cluster - sub cycle, and means applying said cluster – sub cycle offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if  
25 said unit operation is part of said cluster – sub cycle.

17. The system of Claim 16 further comprising means for defining the nesting of 2 or more cluster – main cycles with respective cluster – sub cycles within each other, means for determining a cluster – main cycle offset for scheduling two or  
30 more unit operations and their respective tasks associated with a nested cluster –

- main cycle, means for determining a cluster – sub cycle offset for scheduling two or more unit operations and their respective tasks associated with a cluster – sub cycle that is in turn associated with a respective nested cluster – main cycle, and (4) applying said cluster – main cycle offsets and associated cluster – sub cycle offsets to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said nested cluster – main cycle and/or respective cluster – sub cycle.
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18. The system of Claim 17 further comprising means for defining a unit operation– main cycle within a nested or non-nested cluster – main cycle and/or associated cluster – sub cycle, a batch cycle or a lot cycle,, means for determining a unit operation offset for scheduling said one or more tasks associated with a unit operation– main cycle, and means for applying said unit operation offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said unit operation– main cycle.
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19. The system of Claim 18 further comprising means for defining a unit operation – sub cycle within unit operation – main cycle, a nested or non-nested cluster – main cycle and/or associated cluster – sub cycle, a batch cycle or a lot cycle, means for determining a unit operation offset for scheduling said one or more tasks associated with a unit operation – sub cycle, and means for applying said unit operation offset to a CCPS associated with each said unit operation in order to schedule said tasks within said process time line if said unit operation is part of said unit operation – sub cycle.
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20. The system of Claim 19 wherein the batch process manufacturing facility is a biopharmaceutical batch processing facility.